

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/812,849	ZANKEL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	DANIEL KOLKER	1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/14/09.
2. ☒ The allowed claim(s) is/are 17-19,21,22 and 58-64.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date <u>20090324</u>.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
|---|---|

/Daniel E. Kolker/  
Primary Examiner, Art Unit 1649  
March 24, 2009

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### **EXAMINER'S AMENDMENT**

1. The remarks and amendments filed 14 January 2009 have been entered. Claims 17 - 19, 21 - 22, and 58 - 64 are pending.

### ***Election/Restrictions***

2. The requirements for election of species labeled as B) and C) on p. 2 of the office action mailed 16 May 2006, i.e. the requirement to elect a single disorder as recited in claims 21 and 59, and a single agent as recited in claims 22 and 60 - 61, are hereby withdrawn. Claim 22 is rejoined and will be examined in its entirety.

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Katherine Neville on 24 March 2009.

4. The application has been amended as follows:

In the specification:

At p. 1, line 1, the title has been changed to

- - Methods of increasing delivery of active agents to brain comprising administering receptor associated protein (RAP) fragments conjugated to active agents - - -

5. In the claims:

In claim 17, line 5, delete the words "wherein said RAP polypeptide retains megalin-binding activity and"

In claim 18, line 4, change "of-an" to - - of an - - -

In claim 18, line 5, delete the words "wherein said RAP polypeptide retains megalin-binding activity and"

In claim 61, line 4, change "Leukaemia" to - - Leukemia - - - and change "TGFb" to - - TGFβ - - -

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In claim 61, line 5, change "TGFa" to -- TGF $\alpha$  --

6. The following is an examiner's statement of reasons for allowance:

The rejections of record under 35 USC 103(a) are withdrawn. The examiner concedes that Neels does not disclose that RAP is transcytosed by LRP, but rather teaches away in that the reference indicates that RAP likely binds to LRP in such a manner as to occupy multiple receptor domains beyond the ligand binding domain (p. 31310). Given this teaching, along with the failure by any reference cited to indicate that RAP is transcytosed by LRP, the rejections are withdrawn.

The amendments of claims 17 and 18 above are sufficient to overcome the written description rejections of record. According to the guidance set forth by the USPTO's Written Description Training Materials (available at <http://www.uspto.gov/web/menu/written.pdf>), claims drawn to variants of identified protein sequences, expressed in terms of percent identity, and without recitation of specific functions, are considered described. See in particular Example 11A, beginning on p. 37 of that document.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker/

Primary Examiner, Art Unit 1649

March 24, 2009